Supreme Court, U. S.
F I L E D
APR 12 1999
CLERK

No. 98-1424

In The

Supreme Court of the United States

October Term, 1998

COLLAGEN CORPORATION,

Petitioner,

v.

CHARLOTTE KENNEDY and ROBERT KENNEDY,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITIONER'S REPLY MEMORANDUM

FREDERICK DOUGLAS BAKER
Counsel of Record
KATHLEEN D. PATTERSON
SEDGWICK, DETERT, MORAN & ARNOLD
One Embarcadero Center, 16th Floor
San Francisco, California 94111-3628
Telephone: (415) 781-7900

Counsel for Petitioner

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

1809

TABLE OF CONTENTS

Page

PETITIONER'S REPLY MEMORANDUM 1

A. CERTIORARI SHOULD BE GRANTED TO DECIDE THE ISSUE OF INDEPENDENT VALIDATION 1

1. The Ninth Circuit's Opinion Is At Odds With *Daubert* On A Critical Issue That Divides The Circuits 1

2. The Issue Is Properly Before The Court .. 4

B. CERTIORARI SHOULD BE GRANTED TO DECIDE THE BURDEN OF PROOF ISSUE ... 5

C. CERTIORARI SHOULD BE GRANTED TO DECIDE WHETHER *DAUBERT* ESTABLISHES A STANDARD OF CERTAINTY FOR EXPERT CAUSATION TESTIMONY THAT SUPERSEDES SUBSTANTIVE STATE LAW 5

CONCLUSION 6

TABLE OF AUTHORITIES

Page

Federal Cases

Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378 (4th Cir. 1995) 3

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995) 2, 3, 4, 5

General Electric Co. v. Joiner, 522 U.S. 136, 118 S.Ct. 512 (1997) 3

In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717 (3d Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995) 3

Kumho Tire Co. v. Carmichael, ___ U.S. ___, 1999 WL 153445, No. 97-1709 (March 23, 1999) 4

Mitchell v. Gencorp Inc., 165 F.3d 778 (10th Cir. 1999) 3

Moore v. Ashland Chemical, Inc., 151 F.3d 269 (5th Cir. 1998) (*en banc*) 3

Teague v. Lane, 489 U.S. 288 (1989) 6

Zuchowicz v. United States, 140 F.3d 381 (2d Cir. 1998) 3

PETITIONER'S REPLY MEMORANDUM

A. CERTIORARI SHOULD BE GRANTED TO DECIDE THE ISSUE OF INDEPENDENT VALIDATION

The Petition first presents this question: Does Rule 702 require the proponent of an expert opinion – an opinion that concededly (i) finds no support in the consensus view of either a majority or an acknowledged minority of experts in the field, (ii) finds no support in the published medical and scientific literature, and (iii) was not developed out of research but instead was formulated solely for litigation – to establish by independent validation that the methodology employed by the expert is scientifically reliable?

Kennedy does not contest the factual predicates. She in essence concedes that her hired-gun expert's opinion is no more than one man's belief, and that no other expert source – no text, no journal, no published study, no other expert witness – attests to the reliability of the expert's methodology.

Kennedy's brief in opposition attempts to persuade the Court not to review this issue for two substantive reasons. (Br. in Opp., pp. 3-5.) Neither has merit.

1. The Ninth Circuit's Opinion Is At Odds With *Daubert* On A Critical Issue That Divides The Circuits

Kennedy attempts to downplay the significance of the Ninth Circuit's error, and to ignore the conflict that

divides the circuits, in a discussion of "objective verification" and "independent validation" that is profoundly confused. (Br. in Opp., pp. 3-4.) Kennedy's confusion mirrors that of the Ninth Circuit – neither has drawn the necessary distinction between: (1) objectively verifiable facts or data, and (2) independent validation of the expert's methodology.

For example, as mentioned briefly in the Petition (p. 22), during the summer months there is a dramatic increase in watermelon consumption and in deaths by drowning. Suppose that a drowned man's heirs bring an action against a seller of watermelon; in response to a summary judgment motion, the heirs submit a physician's affidavit stating that he has studied the statistical data on summer drownings and watermelon consumption, he has examined the body and found that death was by drowning and the decedent consumed watermelon within 48 hours of death, and it is his opinion – to a reasonable degree of medical probability – that watermelon caused the drowning.

No doubt the statistics were accurate. So too the results of the examination. These facts and data are subject to objective verification. But could the heirs conceivably establish by **independent validation** that the physician's **methodology** – the formulation of a causation opinion based upon a spurious statistical association – is supported by the consensus view of other experts and the medical literature? Of course not.

In *Daubert II* (*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995)) the court said "the party proffering the evidence

must explain the expert's methodology and demonstrate in some **objectively verifiable** way that the expert has chosen a **reliable scientific method** and followed it faithfully." *Daubert II*, 43 F.3d at 1319 (emphasis supplied).

In *Kennedy* the court accepted the expert's opinion because he "relied upon a wide variety of objective, verifiable **evidence** in forming his opinion." (Pet. App., p. 5.) Following this statement, the court recites a litany of **data** the expert looked at. (Pet. App., p. 6.) What is utterly lacking – notwithstanding the court's pronouncement that the expert "used the traditional scientific methodology" (Pet. App., p. 6) – is **any** evidence that **any** expert in the field would look at the same data and reach the same conclusion.

There indisputably was not, in short, **any** independent validation – as *Daubert II* requires – for the expert's analytical leap from data to conclusion. See *General Electric Co. v. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 519 (1997).

The split of authority on the question whether independent validation of an expert's **methodology** is required in a case such as this extends beyond the Ninth Circuit. The Fifth Circuit and the Tenth Circuit require such validation. *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269 (5th Cir. 1998) (*en banc*); *Mitchell v. Gencorp Inc.*, 165 F.3d 778 (10th Cir. 1999). The Second Circuit, the Third Circuit, and the Fourth Circuit do not. *Zuchowicz v. United States*, 140 F.3d 381 (2d Cir. 1998); *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), *cert. denied*, 513 U.S. 1190 (1995); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378 (4th Cir. 1995).

The issue is of significant importance. The conflict among the circuits is irreconcilable absent the Court's review. Kennedy had made no reasoned argument to the contrary. The Court should grant certiorari and resolve the issue.[1]

2. The Issue Is Properly Before The Court

Respondent's suggestion that the issue of independent validation of an expert's methodology was not raised below (Br. in Opp., pp. 4-5) is fatuous. The issue was addressed by the district court (Pet. App., p. 18), was briefed in the court of appeals (Reply Mem. App., *infra*, pp. 2-10), and was addressed, albeit wrongly, by the court of appeals (Pet. App., pp. 5-11).

---

[1] Respondent raises the Court's recent decision in *Kumho Tire Co. v. Carmichael*, ___ U.S. ___, 1999 WL 153445, No. 97-1709 (March 23, 1999). (Br. in Opp., pp. 3-4.) Although *Kumho* does not directly address the issue raised by the Petition, it is significant here in one important respect. The district court here carefully reviewed the evidence, applied the principles of *Daubert I* and *Daubert II*, and concluded the expert's testimony was inadmissible. (Pet. App., pp. 14-21.) While the Ninth Circuit looked at the same evidence and drew a different conclusion, by no stretch of the imagination did the district court abuse its discretion under the standard established in *Kumho*: "[W]e conclude that **the trial judge must have considerable leeway** in deciding in a particular case how to go about determining whether particular expert testimony is reliable. . . . [W]hether *Daubert*'s specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge **broad latitude** to determine." *Kumho*, 1999 WL 152455 at *10, *11 (emphasis supplied).

B. CERTIORARI SHOULD BE GRANTED TO DECIDE THE BURDEN OF PROOF ISSUE

Collagen contends the proponent of expert testimony bears the burden of establishing, by a preponderance of the evidence, independent validation of the expert's **methodology**. This contention is supported by *Daubert II* and many federal district courts around the country. (See Pet., pp. 26-27 and cases there cited.)

It is undisputed there was no such evidence here. On that basis alone, under the prevailing view, the district court's ruling should have been affirmed. But it was not, the court of appeals stating that "Collagen has not introduced any evidence that Dr. Spindler's reasoning is not scientifically valid." (Pet. App., p. 10.)

By any reasoning, this is a 180-degree reversal of the burden of proof. Respondent's attempt to cast this as merely "an evidentiary issue" (Br. in Opp., p. 5) is unsupported by law or logic, and simply makes no sense.

C. CERTIORARI SHOULD BE GRANTED TO DECIDE WHETHER *DAUBERT* ESTABLISHES A STANDARD OF CERTAINTY FOR EXPERT CAUSATION TESTIMONY THAT SUPERSEDES SUBSTANTIVE STATE LAW

The Petition establishes that the Ninth Circuit ignored California's "more likely than not" requirement for an expert opinion on causation, substituting instead a vague "something less than a high degree of certainty" standard purportedly drawn from *Daubert*. (Pet., pp. 27-30.)

Kennedy's only response is to contend that because the Court denied certiorari in an earlier appeal where the Ninth Circuit made the same error, the Court "has no jurisdiction" to consider the issue, which is not "moot." This suggestion is, of course, shockingly misinformed:

> As we have often stated, the 'denial of a writ of certiorari imports no expression of opinion upon the merits of the case.' *United States v. Carver*, 262 U.S. 482, 490, 43 S.Ct. 181, 182, 67 L.Ed. 361 (1923) (Holmes). The 'variety of considerations [that] underlie denials of the writ,' *Maryland v. Baltimore Radio Show*, 338 U.S. 912, 917, 70 S.Ct. 252, 254, 94 L.Ed. 562 (1950) (opinion of Frankfurter, J.), counsels against according denials of certiorari any precedential value.

Teague v. Lane, 489 U.S. 288, 296 (1989) (additional citations omitted).

Kennedy does not dispute the substance of Collagen's Petition with respect to this issue. Her contention that the Court "has no jurisdiction" to consider the issue is facially preposterous.

CONCLUSION

The petition for writ of certiorari should be granted.

DATED: April 9, 1999

Respectfully submitted,

SEDGWICK, DETERT, MORAN & ARNOLD
FREDERICK D. BAKER

Attorneys for Petitioner
Collagen Corporation

App. 1

No. 97-16945

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CHARLOTTE KENNEDY and ROBERT KENNEDY,

Plaintiffs and Appellants,

v.

COLLAGEN CORPORATION, et al.,

Defendants and Appellees.

On appeal from the United States District Court
for the Northern District of California
(No. CV-89-02331-CAL)

Honorable Charles A. Legge,
United States District Judge

APPELLEES' BRIEF

FREDERICK D. BAKER
KATHLEEN D. PATTERSON
KIRK C. JENKINS
SEDGWICK, DETERT, MORAN
& ARNOLD
One Embarcadero Center,
16th Floor
San Francisco, California 94111
Telephone: (415) 781-7900

Attorneys for Appellee
COLLAGEN CORPORATION

* * *

D. THE TESTIMONY OF SPINDLER IS NOT ADMISSIBLE UNDER DAUBERT, SO SUMMARY JUDGMENT WAS PROPERLY GRANTED

In order to be admissible under *Daubert*, Spindler's opinion that exposure to Zyderm caused Kennedy's injuries must meet two tests. First, Spindler's testimony must reflect "scientific knowledge," his findings must be "derived by the scientific method," and his work product

---

12/ (. . . continued)

F.3d 711, 716 (9th Cir. 1997), this Court decided that testimony about the modus operandi of criminals was "specialized knowledge" of law enforcement, not scientific knowledge. *United States v. Cordoba*, 104 F.3d 225, 230 (9th Cir. 1996) is identical. In *Thomas v. Newton International Enterprises*, 42 F.3d 1266, 1269-70 (9th Cir. 1994), this Court found that a longshoreman's testimony about whether a certain condition would be unusual on the docks and whether an experienced longshoreman would anticipate encountering a hazardous condition was "specialized knowledge." *McKendall v. Crown Control Corp.*, 122 F.3d at 807-08 involved the question of whether the testimony of an engineer who had investigated hundreds of forklift accidents that a certain safety device was feasible was "specialized" or "scientific" knowledge. In *United States v. Bighead*, 128 F.3d 1329, 1330 (9th Cir. 1997), this Court found that an expert's testimony about the characteristics she had observed in the more than thirteen hundred alleged victims of childhood sexual abuse she had interviewed was "specialized" knowledge. *Tyrus v. Urban Search Management*, 102 F.3d 256, 263 (7th Cir. 1996) holds that *Daubert* is applicable to a social science expert, but that the "measure of intellectual rigor" required of a particular witness will depend in part upon her field of expertise.

must amount to "good science." *Daubert I*, 509 U.S. at 589-90, 593-94; *Daubert II*, 43 F.3d at 1315. Second, Spindler's testimony must be " 'relevant to the task at hand,' " i.e., it must logically advance a material aspect of Kennedy's case. *Daubert I*, 509 U.S. at 591; *Daubert II*, 43 F.3d at 1315. The district court ruled that Spindler's testimony was inadmissible pursuant to the first prong of the *Daubert* test, and therefore never reached the second issue. In fact, Spindler's testimony meets neither prong of the *Daubert* test.

1. Spindler's Testimony is Not Scientific Knowledge Derived By the Scientific Method, and Therefore Fails the First Prong of the Daubert Test

a. The *Daubert* Factors

In *Daubert I*, the Supreme Court discussed several factors which a federal court could consider in determining whether a proposed expert's testimony was "good science" derived by the "scientific method." "[A] key question to be answered," the Court observed, is "whether [the theory] can be (and has been) tested." A court should consider the known or potential rate of error in the hypothesis. The court may properly consider whether a theory is generally accepted in the scientific community, and a theory which has attracted " 'only minimal support' . . . may properly be viewed with skepticism." Finally, a court may consider whether or not the theory has been subjected to peer review and publication. *Daubert I*, 509 U.S. at 593-94.

On remand in *Daubert*, this Court noted that a "very significant fact" in determining whether an expert's testimony was "good science" was whether or not his proposed testimony grows naturally and directly out of research he has conducted independent of the litigation, or whether he has developed his opinions expressly for the purpose of testifying. *Daubert II*, 43 F.3d at 1317. If the expert *has* developed his opinions solely for his testimony, then the proponent of the evidence "must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.' " *Id.* at 1317-1318.

b. Spindler's Causation Theory Was Developed Expressly For the Purpose of Testifying, and Has Not Been Peer Reviewed or Published

Kennedy claims that Spindler's theory has been published. *See* "Association Between Bovine Collagen Dermal Implants and a Dermatomyositis or a Polymyositis-Like Syndrome," *Annals of Internal Medicine*, Vol. 118, No. 12 (June 15, 1993). (Appellants' Ex., Tab C, Exh. B thereto.) But as the district court recognized, that article offers no support to Spindler's theory that exposure to Zyderm can cause SLE or "atypical SLE."

Spindler's article purports to describe nine patients who developed "dermatomyositis ["DM"] or polymyositis-like ["PM"] syndrome" after exposure to Zyderm or Zyplast (another product manufactured by Collagen). According to the authors, the conditions (DM/PM) are autoimmune disorders which they describe as

"uncommon . . . myopathologic abnormalities. . . . " (*Id.* at p. 920.) There is no evidence in this case, however, that Kennedy has either dermatomyositis or polymyositis. All available evidence, provided by Kennedy's own experts, establishes that she does not. (Dkt. 198, Exh. O, 48:5-11; Exh. P, 17:11-26; 18:1-4; Appellees' Ex., 153, 159-60.).

Cross-examined about his article, and its relevance to *this* case, Spindler admitted that:

(1) the article was confined to a patient population that had DM/PM, *not* SLE (Dkt. 198, Exh. N, 76:25-77:7; Appellees' Ex., 138-39);

(2) Kennedy did *not* have a delayed hypersensitivity response to collagen (as had eight of the nine DM/PM patients) (Dkt. 198, Exh. N, 77:13-20; Appellees' Ex., 139);

(3) Kennedy did *not* have human Leukocyte Antigens (HLA) as did the DM/PM patients. (Dkt. 198, Exh. N, 79:13-80:12; Appellees' Ex., 141-42); and

(4) Kennedy did *not* have proximal muscle weakness, as did the DM/PM patients. (Dkt. 198, Exh. N, 80:13-24; Appellees' Ex., 142.)

Spindler conceded: "We're talking here [in the case of Kennedy] about a *different* autoimmune disorder," *one which was not the subject of the study.* (Dkt. 198, Exh. N, 80:13-24; 81:1-6; Appellees' Ex., 142-43.)

Spindler's article does not support his claim that Zyderm can cause SLE or "atypical SLE." Kennedy is the only patient he has ever examined who was both exposed to Zyderm and claimed to have either disorder. (Dkt. 198, Exh. N, 75:14-18; Appellees' Ex., 137.) Since Spindler's

theory has not been subjected to peer review and publication, Kennedy must produce "objective, verifiable evidence" that Spindler's opinion is based upon " 'scientifically valid principles.' " Otherwise, Spindler's testimony is inadmissible.

c. Kennedy's Own Experts Admit That Spindler's Theory Has Not Been, and Cannot Be, Tested

According to Spindler, Kennedy has "atypical SLE." His diagnosis is based on the fact that her constellation of signs and symptoms do not meet the minimum criteria for the diagnosis of true SLE. (Dkt. 193, Exh. L, 18:7-25, 19:1; Appellees' Ex., 104-05.) Both he and plaintiffs' expert Dr. Masi say that "atypical SLE" is recognized as a disease entity within the rheumatology community, but neither offers any foundation or explanation for that opinion. (Appellants' Ex., Tab D, Exh. 1, ¶ 5.) In fact, both Spindler and Masi admit that neither the American College of Rhuematology or anyone else has a standard or accepted criteria for what constitutes "atypical SLE." (Appellants' Ex., Tab D, Exh. 1, ¶ 4.)

Apparently, then, "atypical SLE" is an umbrella term for any lupus-like autoimmune disease which a physician cannot diagnose. Spindler admits there is no "signature disorder" to suggest that the cause of "atypical SLE" is collagen exposure or even that the cause is the same for all women with similar signs and symptoms. (Dkt. 198, Exh. N, 162:20-25, 163:1-25; 164:1-6; Appellees' Ex., 145-47.)

Given the vagueness of the term "atypical SLE," it is hardly surprising that not one epidemiological or animal study has ever shown that Zyderm causes SLE or "atypical SLE." (Dkt. 193, Exh. L. 61:5-62:12, 65:12-20; Appellees' Ex., 111-13.) In fact, both Spindler and Dr. Masi admit that without standard criteria for diagnosis, no epidemiological study *can* be done, because it would be impossible to compare the number of cases of "atypical SLE" in the zyderm-exposed population with the number of expected cases of "atypical SLE" in the non-exposed population. (Appellants' Brief at 21; *see* Appellants' Ex., Tab D, Exh. 1, ¶ 4.) Obviously, the lack of any consensus as to exactly what constitutes "atypical SLE" would introduce an enormous rate of error into any such study.

The court disposed of similar claims that "atypical" autoimmune diseases are caused by silicone breast implants in *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. 1387 (D.Or. 1996). Granting defendants' motion to exclude any expert testimony on medical causation, the court found it significant that:

> (1) criteria for "atypical connective tissue disease" ("ACTD"), although proposed, had not been tested;
>
> (2) there was no "signature disorder" to suggest the cause of ACTD was silicone exposure or that the cause of the signs and symptoms of ACTD was the same for all women; and
>
> (3) plaintiffs' hypothesis that silicone breast implants caused ACTD had not been tested epidemiologically.

Id. at 1402.

On the basis of these facts, conceded by plaintiffs' experts as they are conceded here, the court concluded:

> *Because ACTD is at best an untested hypothesis, there is no scientific basis for any expert testimony as to its causes and presence in plaintiffs.* Therefore, defendants' motions are granted as regards any expert testimony relating to the existence and causation of any atypical, silicone-caused auto-immune disorder.

Id. (emphasis supplied).

Spindler's theory that Zyderm causes "atypical SLE" is, like plaintiffs' theory of silicone-caused ACTD in *Hall*, an untested hypothesis based upon the only patient Spindler has ever examined with both Zyderm exposure and "atypical SLE": Kennedy. "Case reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls." *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. at 1411, citing *Casey v. Ohio Medical Products, supra*, 877 F.Supp. 1380; *Muzzey v. Kerr-McGee Chemical Corp.*, 921 F.Supp. 511, 519-20 (N.D. Ill. 1996); *In re Three Mile Island Litigation Cases Consolidated II*, 911 F.Supp. 775, 795-96 (M.D. Penn. 1996); *Grimes v. Hoffman-LaRoche, Inc.*, 907 F.Supp. 33, 35 n.2 (D.N.H. 1995). Therefore, an analysis of case reports "cannot be the basis of an opinion based on scientific knowledge under *Daubert*." *Hall v. Baxter Healthcare Corp.*, 947 F.Supp. at 1411.

Spindler is being offered to testify to a hypothesis which, by his own admission, has not been and cannot be tested. The district court correctly found that Spindler's hypothesis that Zyderm causes "atypical SLE" is unreliable, inadmissible and insufficient to create a triable issue

of fact in regard to causation. *See Hall v. Baxter Healthcare Corp.*, 947 F.Supp. at 1406.

d. ~Spindler's Theory Has Attracted No Support in the Scientific Community

Finally, Spindler's theory that Zyderm causes SLE or "atypical SLE" has attracted no support whatsoever in the scientific community. As noted above, no epidemiological or animal study has ever found any association between Zyderm and SLE or "atypical SLE." There is no consensus in the rheumatologic community that Zyderm causes SLE. (Dkt. 193, Exh. L, 60:9-17; Appellees' Ex., 110.) Nor was Spindler able to point to any textbooks which say that Zyderm causes SLE or "atypical SLE." (Dkt. 193, Exh. L. 67:11-14; Appellees' Ex., 115.)

The district court correctly found that *none* of the various factors discussed in *Daubert I* and *Daubert II* weigh in favor of a finding that Spindler's testimony is based on "scientifically valid principles." Spindler's testimony was properly excluded, and summary judgment should be affirmed.

* * *

proposition, *Moore v. Ashland Chemical*, has been vacated for *en banc* review by the Fifth Circuit.

Spindler's opinion is untested and untestable speculation with no basis in the scientific method. The district court correctly found that *none* of the *Daubert* factors weigh in favor of a finding that Spindler's methodology is reliable. But even if that decision were erroneous, Spindler does not give his causation opinion to the level

of certainty required by California law, so Spindler's testimony is inadmissible under the "fit" prong of the *Daubert* test as well.

The judgment should be affirmed in all respects.

Dated: February 6, 1998.

Respectfully submitted,

SEDGWICK, DETERT, MORAN & ARNOLD

By /s/ Frederick D. Baker
Frederick D. Baker

Attorneys for Appellee
COLLAGEN CORPORATION